K070894

tepha

APR 13 2007

840 Memorial Drive
Cambridge, MA 02139
tel: (617) 995-5400
fax: (617) 995-5401

Section X
Summary of Safety and Effectiveness

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Tepha, Inc. is submitting the following summary of information respecting safety and effectiveness:

Trade Name: TephaFLEX® Surgical Mesh

Sponsor:
Tepha, Inc.
840 Memorial Drive
Cambridge, MA 02139
Telephone: 617.995.5400
Fax: 617.995.5401

Device Classification Name:
CFR §878.3300
Absorbable Poly-4-hydroxybutyrate (P4HB) Surgical Mesh

Classification: According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.

Predicate Devices:
Ethicon, Inc. - Vicryl Mesh – K810428, K851086
Tepha, Inc. - TephaFLEX Absorbable Suture – K052225
MAST Biosurgery, Inc. – Surgi-Wrap Film – K031995, K050332

Device Description: TephaFLEX® Surgical Mesh is to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. This includes, but is not limited to the following procedures: vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and sacral colposuspension.

Safety and Performance: Physical testing was performed on the TephaFLEX® surgical mesh which determined the TephaFLEX mesh to be substantially equivalent to the mechanical strengths of the predicate devices under indication for use conditions.

Conclusion: Based on the indications for use, technological characteristics, and safety and performance testing, the TephaFLEX® Surgical Mesh has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tepha Incorporated
% Ms. Mary P. LeGraw
Director, Regulatory Affairs
840 Memorial Drive
Cambridge, Massachusetts 02139

APR 13 2007

Re: K070894
Trade/Device Name: TephaFLEX® Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: March 29, 2007
Received: March 30, 2007

Dear Ms. LeGraw:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): Not Assigned

Device Name: TephaFLEX® Surgical Mesh

Indications for Use:

TephaFLEX® Surgical Mesh is intended wherever temporary wound support is required, to reinforce soft tissues where weakness exists or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. This includes, but is not limited to the following procedures: vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and sacral colposuspension.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070894

Prescription Use: X AND/OR Over-The-Counter ___
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)